Editorial

ISAT trial [1]
EBM Rescues Common Sense
Is Experience a Romantic Concept?

Nearly 100 000 arterial aneurysms have been embolised [2]. This is a considerable body of experience accumulated over the last ten years by specialists from around the world. Most of them work in leading institutions, many of them refused to take part in the trial. If such evidence is not good enough to serve patients, this implies that there are several unacceptable practices that need to be made known:

- by industry that keeps on selling a product that is not giving at least as good results as expected vis-à-vis the natural disease history or alternative treatments; some of them even offer practical training sessions and hospital on site assistance;

- by doctors who practice without realizing that they offer less than before;

- by the societies that despite ongoing talks, invited conferences and panels on the treatment by well recognized experts continue to comment, recommend or promote improper management;

- by "sister" specialities that let improper treatment replace the existing one, in place and improved over so many years and performed by trained and certified professionals;

- by administrations that cover these practices and increase their functioning cost in a dramatic fashion forcing resources to be redeployed in many places, without being convinced by the everyday management of these patients for ten years.

If embolization protects as much as surgery against rebleeding in bad grade ruptured arterial aneurysms over time, without the need for evidence, why was it needed for the good grades (which represent the bulk of randomized cases)? The trial was not designed to demonstrate that coiling is acceptable for arterial aneurysm treatment. It was to provide definitive proof that coiling is better than clipping in good grade aneurysms. It is obvious that excluding a good grade arterial aneurysm by endovascular technique is as easy (if not easier) as for a bad grade aneurysm. It sounds like the micro AVMs where the best morphological results are obtained. The problem of clip versus coil is primarily technical. We do not deal with difficult arterial aneurysms that could be better treated by such or such approach: the evidence for those is already gained. We deal with a niche of cases where the quality of the results obtained is the most rewarding with nearly all patients doing well.

Why a randomized study?

"Randomized studies of a sufficient size are essential if accurate and objective information and advice is to be provided to patients and their relatives to decide which treatment course to pursue" [1].

We may suspect, however, that updated professionals are aware of results

when they reach 100 000 cases. Obviously our populations and politicians need evidence that cannot be discussed. Thus an undebatable statement (randomized study published in a high impact factor publication) offered evidence for an unaware or resistant population. Yet experience was sufficient for some and the trial appeared to them unnecessary. Some experts expressed their ethical concerns when coilable patients were randomized for surgery. That opinion based on expertise and empirism could not be considered sufficient, it had not reached the undebatable factual level of evidence. Unfortunately, it turned out to be confirmed rapidly as the randomization concluded faster than the expected time for the trial to demonstrate it. Was the price paid to convince a skeptical portion of the medical community justified?

To be accepted today, "facts" must be presented in a dual, manichean way, nuances are avoided because they create confusion. Yet the exactitude of the proof does not make it an immediate and durable universal truth. The information pointing to what is better (or good), what is worse (or bad), results in a doctrinal position. It introduces violence in the debate. That new doctrine imposes submission through evidence (le neoliberalisme c'est le marxisme privé, JF Kahn). Such situations engender what is called "campism": an issue is reduced to a factual statement that is simple enough to identify two camps those for and those against.

Measuring the effect of the clipping or coiling decision on patients measures the consequences of the absence of agreement in 20% of situations. (10000 patients were admitted to the participating centers, and for 80% of them a single treatment strategy was agreed by both specialists). Each time we need evidence-based medicine instead of common sense, intellectual debate and personal questioning, we express a society or community failure. Measuring and concluding with rules for subjective matters restricts the value of sense and by overruling ends up reducing our capacity for observation and ultimately freedom. The 20% of undetermined therapeutic choice suggests insufficient communication and competing interests between specialists.

The question raised is certainly correct, but late: the answer had become predictable, but its consequences are largely underestimated. The recommendations issued by this randomized study having the power of the law create a dangerously unbalanced legitimacy and right.

The patients benefit?

The patients benefit may not be the expected one. The conclusions on ruptured arterial aneurysms will be immediately and wrongly extended to unruptured ones.

Aneurysmal diseases being different, individual training being different, referral being different, team relationships being different, economic resources being different, financial interest being different, can the trial conclusions apply without severe restrictions? Certainly not, but the overall results dilute these differences implying that the conclusions are largely valid and applicable. Material vigilance shows that most of the devices approved are industrially safe, but potentially dangerous by misuse. Are interventionists going to give information on their results to allow patients "to decide which treatment to pursue"? [1]*. Will they refer patients to a centre offering the expected level of results or simply to coiling? Shall "hands on" training be improvised to limit the consequences of the new decisions? To deserve a result of that importance, proper training is required enhancing the crucial role played by no technical patients selection and the best possible knowledge of the disease.*

"The results of this trial should not be interpreted as indicating that Neurosurgery for arterial aneurysms should cease" [1]*. This seems wise, but the second half of the sentence reveals the mechanical side of the decision. "There will be a proportion of patients who for clinical or anatomical reasons are unsuitable for coil treatment …"* [1]*.*

The sensible and realistic suggestion should be that even when coilable, some arterial aneurysms will still be operated if the available local human resources are not at the expected quality level. The lack of balanced vision in the conclusions, will lead to another extreme: any operator will be justified to coil arterial aneurysm patients even if working close to a highly competent neurosurgeon simply by referring to published evidence. From the same common sense and experience (that has been made acceptable by virtue of EBM), self-evaluation and limitation are unlikely to occur. Other evaluations are likely to be commended to demonstrate that today the uncertified competence of interventional neuroradiologists could not support such a conclusion. Obviously, the question will not be phrased in this way but will probably invoke the demography of interventionalists and

the need for emergency treatments. The price to pay (again by patients) will be another randomized study or the deemed inevitable learning curve.

"New devices will come to improve "durability, but are unlikely to have any significant impact on procedural morbidity" [1].

Does durability need to be improved? Again there is expert experience showing that proper patient selection can predict the long term results of coiling. Results reported in many series suggest insufficient patient selection for arterial aneurysm embolization. Within the coiled arterial aneurysms, there are subgroups where morbidity is probably too high in comparison to surgery. Recognition of these subgroups may require new tools, but proper selection capacity should be shown first. If the population of arterial aneurysms included is large, patients' interest (leaning on disease subgroups) is diluted into wider considerations within market sizes of polyvalent tools. The formatting of the diseases to the tools ("It is not because we have a hammer that everything looks like a nail") precedes the formatting of the doctors to the tools, and that of the doctors to the market.

In some places, this trial will have no consequence in terms of practice; it will only impact on the psychology of the interprofessional and patient-doctor relationships. The use of coils is exposed to pockets of resistance and cultural inertia in which the debate pits personal interest against commercial ones. Where the medical system is public, the question was seldom raised unless there was local individual resistance; where interventional neuroradiology is performed by neurosurgeons the problem was not relevant. Conversely, where the experience with coils has mostly been gained on poor grades and large-sized arterial aneurysms, the reluctance to extend coil indications is maximum. There are even places where coils cannot be chosen because neurosurgeons oppose them regardless of the evidence; and finally places that can simply not afford the price of the coils. The same non scientific issues leading to endless dissertations requiring randomized study apply to brain AVMs, Spinal Cord AVMs and stroke management.

Most of these debates are rhetorical. We should question ourselves on the consequences of referring to a trial to obtain an independent, objective position to solve a question dominated by competing interests.

Conflict of interest

When evidence is mediated it becomes reality; when aimed at everybody it turns into fiction. When ideology reaches the masses it becomes a material force. These basic observations introduce the last aspect of the consequences of the trial.

The commercial challenge in solvent countries where the resistance to coiling good grade aneurysms was high is significant. Therefore potential conflicts of interest are particularly important. Conflict of interest does not mean lies, guilt, suspicion or impossibility to raise scientific issues in an ethical perspective. However, experts auditing an issue for the public interest, should be independent. Science and the public deserve the same trust and ethical attention. Certain partnerships with industry may appear incompatible with a fully independent evaluation. Private interest versus public interest have to be separated like executive, legislative and jurisdictional powers, or religion and governance.

The choice of the appropriate experts could be made by the scientific societies, which indirectly represent the public interest. Loyal communication should take place with industry to allow transparency and converging ethical concerns as a joint commitment to the public. Such trials would receive a special mark testifying their quality process and monitored independence as a public label.

References

1 Johnston SC, Higashida RT et Al: Recommendations for the endovascular treatment of intracranial aneurysms. A statement for healthcare professionals from the committee on the cerebrovascular imaging of the American Heart Association council on cardiovascular radiology. Stroke 33: 2536-3544, 2002.

2 International subarachnoid aneurysm trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms : a randomised trial. Lancet 360: 1267-1274, 2002.

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